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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,614	01/09/2002	Ya Fang Liu	YFLU-P03-001	6176
23628	7590	03/04/2004	EXAMINER	
WOLF GREENFIELD & SACKS, PC FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2211			WEBER, JON P	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,614

Applicant(s)

LIU, YA FANG

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,36,39,40 and 43 is/are pending in the application.
- 4a) Of the above claim(s) 36,39,40 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/03, 4/22/02</u> | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election of Group I, claims 33-34 in the Paper filed 18 December 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 36, 39-40 and 43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. It is suggested that the non-elected claims be canceled in response to this Office action to expedite prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites "change in physiological status" which is vague and indefinite because the specific parameter of the physiological status that is being monitored is unclear. There are a vast number of possible physiological parameters that could be monitored, but it is not clear which of these would be indicative of ability to inhibit MLK kinase activity and thereby prevent neuronal death.

Claim 33 recites “inhibit MLK kinase activity” which lacks antecedent basis. This claim is drawn solely to a method of determining a compounds ability to inhibit JNK kinase activity. It is not clear how to examine claims 33-34 in view of this discrepancy.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Each of the following references is relied upon because there is nothing in the claims that precludes determining the post treatment physiological state of the animal by biochemical means. These references are relied upon as most relevant, although the broad scope of the claims would have been consistent with a rejection over any reference that disclosed monitoring the physiological state of an animal before and after administering a test compound, whether the test compound affected JNK or not, inasmuch as this is the sole step.

Claims 33-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. (US 5,621,100).

Lewis et al. (US 5,621,100) disclose infusing rodent brains *in vivo* with kainic acid, known to induce neuronal death by apoptosis and to involve JNK. The effect of test compounds

Art Unit: 1651

K-252a or its derivatives on kainate-induced neuronal damage was then evaluated by several means including biochemical (see Example 9, cols 35-37).

Claims 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (US 6,060,247).

Miller et al. (US 6,060,247) disclose initiating neuronal death by apoptosis in experimental animals by well known methods such as axotomy or cerebral ischemia, and then administering test compounds *in vivo* identified as possible therapeutic agents to with a pharmaceutically acceptable carrier, neuronal tissue is isolated from the animals subjected to suitable assays (column 7, lines 50-60).

Claims 33-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Qin et al. (1998).

Qin et al. (1998) disclose injecting quinolinic acid into rat striatum *in vivo* to induce DNA fragmentation and apoptosis. Test animals were given MK801 (dizocilpine) to block the fragmentation. The efficacy was determined by biochemical analysis.

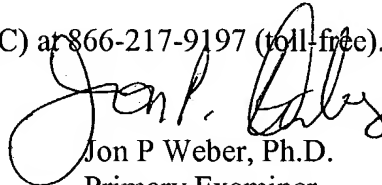
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

Application/Control Number: 10/042,614
Art Unit: 1651

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
24 February 2004